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| 10/582,174 | 06/08/2006 | Keiichi Fujiwara | 0020-5490PUS1 | 8923 |

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| EXAMINER | |
|---|---|
| HUANG, GIGI GEORGIANA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 04/03/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/582,174 | FUJIWARA ET AL. | |
| | Examiner | Art Unit | |
| | GIGI HUANG | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 4-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/2006, 9/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application*

1. Claims 1and 4-21 are present for examination at this time.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-14 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a "granule-like" or "tablet-like" preparations. These terms are indefinite as they are unclear what form is being claimed. The terms are not defined. Regarding the claims, the phrase "granule-like" or "tablet-like" renders the claims indefinite because the claims includes elements not actually disclosed thereby rendering the scope of the claims unascertainable.

4. Claims 12, 14, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a solid composition comprising a particle with excipients but also recite the composition to be a granule which is also a particle. These claims recite a broad limitation together with a narrow limitation and are considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the

invention. It is unclear what the composition form is for the claims. For the purposes of examination, the composition recited is a form comprised of the particles (granules) such as a tablet.

It is noted that claim 19 appears to be a product by process limitation in which only the end product is the limitation for examination. In the instant case, it is not entirely clear the form of the preparation as addressed above, and for the purposes of examination the composition recited is a form comprised of the particles (granules) such as a tablet.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 1, 4-7, and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

It is noted that claim 19 appears to be a product by process limitation in which only the end product is the limitation for examination and as addressed in the 112 rejection above for the purposes of examination, the composition recited is a form comprised of the particles (granules) such as a tablet.

Siebert et al. teaches an oral disintegrable dosage form comprising an active ingredient, sugar or sugar alcohol, binders, disintegrants, and other excipients. The dosage form can be a microgranule, granules, particles, powder, tablets, and capsules.

The active include pharmaceutical ingredients and the formulation is particularly capable of taste masking distasteful drug particles. The sugar or sugar alcohol preferably includes mannitol. The binders preferably include microcrystalline cellulose, starch, and methyl cellulose. Desirable disintegrants include crospovidone. Example 1 is a powder (granular) composition comprising famotidine, mannitol, microcrystalline cellulose (Avicel), and crospovidone that is formed into a tablet (second composition). The ratios for famotidine, mannitol, and binder are based on the amounts of each component. The amount of water is negligible as it is evaporated during granulation. There is 9.09mg of famotidine, 30mg microcrystalline cellulose, and 151.1mg mannitol in the tablet. The ratio of famotidine to the binder is 9.09:30 or 1:3.3. The ratio of binder to mannitol is 30:151.1 or 1:5.04.

The disintegration properties and profiles are intrinsic to the composition. When the components of compositions are met, the properties related to it are the same. The composition is prepared by creating a coating solution (water-containing solvent), the drug (famotidine), is screened, coated while granulated, blending with mannitol, binder, disintegrant, other excipients, screened, mixed, powder is discharged, then tableted.

Siebert et al. does not expressly teach methylcellulose in the example.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute methylcellulose for microcrystalline cellulose, as suggested by Siebert, and produce the instant invention. Siebert teaches that the preferred binders include microcrystalline cellulose and methyl cellulose. It would have be obvious to one of skill in the art to substitute one preferred binder for

another depending on availability or desired properties as they are taught to be analogous.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the binders when motivated by pricing, availability, or desired properties of the binder used to produce the final product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 8-10, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4-7, 11-20 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

The teachings of Siebert et al. are addressed above.

Siebert et al. does not expressly teach the incorporation of D-mannitol or mosapride (4-amino-5-chloro-2-ethoxy-N—[[4-(4-flurobenzyl)-2-morpholinyl]-methyl]benzamide) or a commercial package.

Depui et al. teaches the usefulness and incorporation of mosapride for the treatment of gastro oesophageal reflux disease (GORD, also known as GERD). Depui also teaches that famotidine is known to be used for GORD/GERD (Abstract, Col.1, lines 20-33, 50-65, Col.2, lines 2-4, Col. 7, lines 55-68, Col. 8, lines 1-5, Examples).

Yoshinari et al. teaches that D-mannitol is of high value as an excipient for high moisture sensitivity as it is not hygroscopic and retains no substantial moisture. The D-mannitol produced has excellent compressibility and has versatility as it can be used for direct compression, wet-granulation, or dry-granulation. It can be used as a good excipients for pharmaceutical compounds (Abstract, Col. 1, lines 10-17, Col.4, lines 19-50, Col.8, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute mosapride for famotidine and D-mannitol for mannitol, as suggested by Depui and Yoshinari, and produce the instant invention. Mosapride and famotidine as both used for GORD as taught by Depui, known to have unpleasant tastes (see Siebert above and Yoshioka et al. (WO 2004/066913), pages 2-3), so it would have been obvious to one of skill in the art to substitute mosapride for famotidine as it is routine to use known formulations for analogous drugs, with a reasonable expectation of success. As the composition of Siebert is disintegrable, and thereby sensitive to humidity, it would be obvious to substitute the mannitol with D-mannitol as Yoshinari teaches that D-mannitol is desirable as an excipient for high moisture sensitivity formulations as it is not hygroscopic and retains no substantial moisture.

It is also obvious to place any composition in a package to not only designate what the composition is through labeling, but also for storage, shipping, and stability to stores, pharmacies, and consumers. Written matter for the use of a known drug (mosapride), particularly for an existing use, does not impart patentability. An example of this is a disintegrating tablet formulation of mosapride in a Press Through Pack package disclosed in Shirai et al. (U.S. Pat. No. 6413541, Col. 2, lines 55-65) or packaging of Yoshioka et al.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to optimize the same formulation for analogous drugs to reduce the amount of experimentation, research, and development to lower cost and improve efficiency. It is also desirable to use similar and analogous drugs for the same purpose for composition formulation when motivated by pricing, availability, or desired properties of the final product. It is also desirable for manufacturers place any composition in a package to maintain stability (humidity-desiccants), reduce breakage, and increase ease of storage and shipping to stores, pharmacies, and consumers. Thereby reducing production costs (less breakage and spoilage) and improving acceptable of consumers and distributors. Written matter for the composition, is desirable for manufacturers to ensure that the composition is taken appropriately.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore,

the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## ***Conclusion***

8. Claims 1 and 4-21 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612